10-04-07

AF/IFW

Docket No: AM100459
Patent

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re of Application of:	Burgher, et al.		
Application No.:	10/681,489	Group Art No.:	1615
Filed:	October 8, 2003	Examiner:	Bethany P. Barham
For:	INFANT FORMULA CONTAINING NUCLEOTIDES		
Confirmation No.:	5899		
Customer Number:	25291		

Mail Stop Appeal Brief-Patents
Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL OF APPEAL BRIEF (PATENT APPLICATION - 37 CFR 41.37)

1. Transmitted herewith is the Appeal Brief which is being filed within two months of the filing of the Notice of Appeal, which was filed on August 6, 2007.

2. FEE FOR FILING APPEAL BRIEF
Pursuant to 37 CFR 41.20(b), the fee for filing the Appeal Brief is $500.00.

3. EXTENSION OF TERM
The proceedings herein are for a patent application and the provisions of 37 CFR 1.136 apply.

(complete (a) or (b) as applicable)

(a) ☐ Applicant petitions for an extension of time for the total number of months checked below.

☐	One Month.	Fee in the amount of	$ 120.00
☐	Two Months.	Fee in the amount of	$ 450.00
☐	Three Months.	Fee in the amount of	$ 1,020.00
☐	Four Months.	Fee in the amount of	$ 1,590.00
☐	Five Months.	Fee in the amount of	$ 2,160.00

If an additional extension of time is required, please consider this a petition therefor.

(Check and complete the next item, if applicable)

☐ An extension for months has already been secured and the fee paid therefor of $0.00 is deducted from the total fee due for the total months of extension now requested.

CERTIFICATE OF MAILING 37 CFR §1.10

I hereby certify that this paper and the documents referred to as enclosed therein are being deposited with the United States Postal Service on the date written below in an envelope as "Express Mail Post Office to Addressee" Mailing Label Number **EM 007053263 US** addressed to the Mail Stop Appeal Brief-Patents, Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450.

October 3, 2007
Date

Cecilia Chessell
Cecilia Chessell

☐ Extension fee due with this request: $0

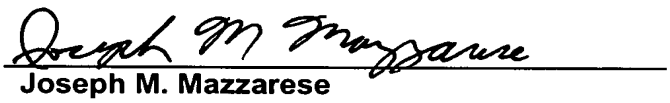
(b) ☒ Applicant believes that no extension of term is required. However, this conditional petition is being made to provide for the possibility that applicant has inadvertently overlooked the need for a petition and fee for extension of time.

4. TOTAL FEE DUE

THE TOTAL FEE DUE IS:	
Appeal brief fee	$500.00
Extension fee (if any)	0
TOTAL FEE DUE:	$500.00

5. FEE PAYMENT

☒ Charge fee to **Deposit Account No. 01-1425**. This is a request to charge for any additional extension and/or fee required or credit for any excess fee paid. A duplicate of this petition is attached.



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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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APPEAL BRIEF PURSUANT TO 37 C.F.R. 41.37

This is an Appeal of the Final Rejection dated May 18, 2007. A Notice of Appeal was filed on August 6, 2007.

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CERTIFICATE OF MAILING 37 CFR §1.10

I hereby certify that this paper and the documents referred to as enclosed therein are being deposited with the United States Postal Service on the date written below in an envelope as "Express Mail Post Office to Addressee" Mailing Label Number **EM 007053263 US** addressed to the Mail Stop Appeal Brief-Patents, Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450.

October 3, 2007
Date

Cecilia Chessell
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Table of Contents

I. Real Party in Interest

The real party in interest is the Assignee, Wyeth, a company incorporated in the State of Delaware.

II. Related Appeals and Interferences

None.

III. Status of Claims

Claims 1-3 and 5-7 have been finally rejected and the rejection of claims 1-3 and 5-7 is being appealed. Claim 4 has been canceled.

IV. Status of Amendments

No amendments have been filed subsequent to final rejection.

V. Summary of the Claimed Subject Matter

Claim 1 is drawn to an infant formula composition comprising 3.2 mg/L to 15.4 mg/L of CMP; 1.8 mg/L to 11.0 mg/L of UMP; 2.4 mg/L to 8.0 mg/L of GMP; 0.1 mg/L to 2.2 mg/L of IMP; and 2.5 mg/L to 13.2 mg/L of AMP (specification page 3, lines 15-27).

Claim 7 is drawn to a method of feeding preterm infants comprising feeding said infant a nutritionally sufficient amount of the infant formula composition of claim 1 (specification page 3, line 29 to page 4, line 21).

VI. Grounds of Rejection

A. Claims 1-7 have been rejected under 35 U.S.C. 102(b) as being anticipated by Gil et al. U.S. Pat. No. 5,066,500. The Examiner has stated in the Office Action dated May 18, 2007 finally rejecting the claims, that Gil et al. teaches:

the limitations of claims 1-3 by teaching an infant formula containing nucleotides (paragraph bridging pages 2-3 of the Action);

the limitations of claims 4-6 by teaching a diet formulation containing 0.2-60 mg/dl nucleotides (middle paragraph of page 2); and,

the limitations of claim 7 by teaching infant formulas and nutrition products

enriched with nucleosides, nucleotides and mixtures thereof to be fed to low birth weight newborns or term healthy infants (paragraph bridging pages 3-4).

B. Claims 1 and 5-7 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Kuhlman et al., U.S. Pat. No. 6,913,778. The Examiner has stated in the Office Action dated May 18, 2007 finally rejecting the claims, that Kuhlman et al. teaches:

the limitations of claim 1 by teaching an infant formula containing nucleotides (paragraph bridging pages 5-6);
the limitations of claims 5-6 by teaching an infant formula having a total nucleotide concentration of 29.5 mg/L (page 6, first paragraph); and,
the limitations of claim 7 by teaching a certain method of feeding an infant (page 6, second paragraph).

VII. Argument

A. Rejection of Claims 1-3 and 5-7 Under 35 U.S.C. 102(b)

The Examiner has erroneously rejected claims 1-3 and 5-7 under 35 U.S.C. 102(b) as being anticipated by Gil et al. U.S. Pat. No. 5,066,500.

35 U.S.C. 102(b) provides that a person shall be entitled to a patent unless "the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States."

1. Claims 1, 5 and 6

"A patent is invalid for anticipation if a single prior art reference discloses each and every limitation of the claimed invention." Schering Corp. v. Geneva Pharmaceuticals, Inc., 67 USPQ2d 1664, 1667 (Fed. Cir. 2003). Gil et al. does not disclose each and every the limitation of claims 1, 5 and 6. Gil et al. describes and claims a more general formulation, but never discloses or claims the specific formulation claimed by Appellant.

Gil, et al. teaches the supplementation of infant formula with nucleosides and/or nucleotides, specifically 0.28-2.8 mg/dl uridine and/or uridine phosphate, 0.04-0.50 mg/dl guanosine and/or guanosine phosphate, 0.64-1.43 mg/dl adenosine and/or

adenosine phosphate, 0.53-1.53 mg/dl cytidine and/or cytidine phosphate, and 0-0.29 mg/dl inosine and/or inosine phosphate.

Nucleotides and nucleosides differ in that nucleotides include phosphate groups, which influences their chemical properties. Gil et al. does not state that any minimum amount of any nucleotide is required. In fact, this patent states that nucleosides are more effective than nucleotides (col. 6, lines 39-51), which would suggest using predominantly, or entirely, nucleosides, rather than the nucleotides of the present invention.

Applicants' invention is an infant formula which comprises the claimed concentrations of the nucleotides CMP, GMP, AMP, UMP and IMP. Nucleosides are not an element of the claims. Nowhere does Gil, et al. teach an infant formula specifically containing these concentrations of these nucleotides. In Gil et al., nucleosides and nucleotides are lumped together without clearly stating how much of each is included. The reference does not specifically set forth concentration ranges of CMP, GMP, AMP, UMP and IMP (nucleotides) for use in an infant formula.

Gil, et al. does state concentrations of CMP, GMP, AMP, UMP and IMP in human milk, including a range of 0.04-0.21 mg/dl GMP, and further states that the patented invention uses nucleosides/nucleotides in the range that they are present in human milk (ref. col 8, lines 61-67). This would seem to suggest that the patented invention should contain 0.04-0.21 mg/dl GMP. Applicants claim a formula comprising 2.4 mg/L to 8.0 mg/L of GMP, which is 0.24 to 0.80 mg/dl. Therefore, the cited reference clearly suggests using less GMP than the claimed invention.

Applicants have discovered that an infant formula comprising the claimed concentrations of CMP, GMP, AMP, UMP and IMP is nutritionally beneficial, and these benefits do not depend on the inclusion of nucleosides. In contrast, the cited reference teaches that nucleosides are preferred to nucleotides, and does not teach that nucleotides alone can provide the desired benefits. Furthermore, this reference teaches away from the GMP concentration claimed by Applicants.

The formulation disclosed in the cited reference simply is not the same as the claimed formulation.

For all the foregoing reasons, Gil, et al. fails to disclose the claimed invention. Therefore, the rejection of claims 1, 5 and 6 is erroneous and should be reversed.

2. Claim 2

Claim 2 is not anticipated by Gil et al. for the same reasons as claim 1, which are set forth above and incorporated here by reference to avoid unnecessary repetition. Because claim 2 is more narrowly drawn than claim 1, the argument that Gil et al. does not describe or claim the same invention is even stronger in the case of claim 2. Gil et al. fails to disclose or claim all the limitations of claim 2.

For all the reasons set forth above, the rejection of claim 2 under 35 U.S.C. 102(b) is erroneous and should be reversed.

3. Claim 3

Claim 3 is not anticipated by Gil et al. for the same reasons as claims 1 and 2, set forth above and incorporated here by reference. Additionally, the range for GMP in claim 3 is 3.0 mg/L to 4.0 mg/L, which is 0.30 to 0.40 mg/dl. This is even farther from the 0.04-0.21 mg/dl GMP range that the cited patent suggests than are the ranges in claims 1 and 2. Gil et al. fails to disclose or claim all the limitations of claim 3.

For all the reasons set forth above, the rejection of claim 3 under 35 U.S.C. 102(b) is erroneous and should be reversed.

4. Claim 7

Claim 7 is a method of feeding preterm infants the formulation of claim 1. Although Gil et al. discloses feeding the reference formula to infants, there is no disclosure in Gil et al. to feed Appellant's formula to infants. The formula of claim 1 is not disclosed in Gil et al., as explained above with regard to the rejection of claim 1 and incorporated here by reference. Therefore, neither is the claimed method of feeding same to preterm infants.

For all the reasons set forth above with regard to claims 1 and 7, the rejection of claim 7 under 35 U.S.C. 102(b) is erroneous and should be reversed.

B. Rejection of Claims 1 and 5-7 Under 35 U.S.C. 103(a)

The Examiner has erroneously rejected claims 1 and 5-7 under 35 U.S.C. 103(a) as being unpatentable over Kuhlman, et al. U.S. Pat. No. 6,913,778.

35 U.S.C. 103(a) provides that, "A patent may not be obtainable though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject mater pertains. Patentability shall not be negatived by the manner in which the invention was made."

1. Claims 1, 5 and 6

The Kuhlman, et al. patent is not directed toward an infant formula that includes nucleotides, but rather, toward an infant formula comprising an increased amount of alpha-lactalbumin; however, it does disclose an example of an infant formula that contains nucleotides. Kuhlman, et al. does not teach or suggest the nucleotide concentration ranges of claims 1, 5 and 6. Although this reference discloses an infant formula containing CMP, GMP, AMP, UMP and IMP, the amount of CMP in the reference formula (16.5 mg/L) is above the range of 3.2-15.4 mg/L in Applicants' claim 1, and the amount of GMP (2.0 mg/L) is below the claimed range of 2.4-8.0 mg/L. Therefore, the invention as a whole is not disclosed.

The scope and content of the cited reference with regard to an infant formula containing nucleotides is extremely narrow - it merely discloses one specific example. Furthermore, the benefits of adding nucleotides is not disclosed in this reference, and there is no disclosure regarding the use of different amounts of nucleotides in an infant formula. Therefore, there would be no reason for one skilled in the art who reads this reference to alter the concentrations to achieve the presently claimed invention. Nothing in this reference would lead or motivate one to make the claimed invention.

For all the foregoing reasons, the cited reference does not render obvious the invention of claims 1, 5 and 6. Therefore, the rejection is erroneous and should be reversed.

2. Claim 7

Claim 7 is a method of feeding preterm infants the formulation of claim 1. Kuhlman et al. does not disclose the formulation of claim 1, as explained above (which explanation is incorporated here by reference). Additionally, the cited reference does not discuss feeding preterm infants. The only suggestion that may be gleaned from this reference with regard to a method of feeding is: to feed the formula shown in the reference to normal term infants, or to infants generally.

Appellant's method is directed to feeding preterm infants a formula that will provide the special nutritional requirements that they need, including certain amounts of nucleotides. Preterm infants have different nutritional requirements than term infants. Kuhlman et al. does not address this issue at all.

Nothing in the cited reference would have motivated one skilled in the art to modify the formula disclosed therein to meet the requirements of claim 1, and then to feed that formula to a preterm infant.

For all the reasons provided above, the cited reference does not render obvious the invention of claim 7. Therefore, the rejection is erroneous and should be reversed.

C. Conclusion

From the foregoing arguments it is evident that the rejections of claims 1-3 and 5-7 are all erroneous. Appellant urges the Board to reverse these rejections and direct the Examiner to allow claims 1-3 and 5-7.

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VIII. Claims Appendix

The claims on appeal are the following:

1. An infant formula composition comprising 3.2 mg/L to 15.4 mg/L of CMP; 1.8 mg/L to 11.0 mg/L of UMP; 2.4 mg/L to 8.0 mg/L of GMP; 0.1 mg/L to 2.2 mg/L of IMP; and 2.5 mg/L to 13.2 mg/L of AMP.

2. The infant formula composition of claim 1, comprising 4.2 mg/L to 11.6 mg/L of CMP; 2.4 mg/L to 8.3 mg/L of UMP; 2.4 mg/L to 6.0 mg/L of GMP; 0.1 mg/L to 1.7 mg/L of IMP; and 3.3 mg/L to 9.9 mg/L of AMP.

3. The infant formula composition of claim 2, comprising 5.3 mg/L to 7.7 mg/L of CMP; 3.0 mg/L to 5.5 mg/L of UMP; 3.0 mg/L to 4.0 mg/L of GMP; 0.1 mg/L to 1.1 mg/L of IMP; and 4.1 mg/L to 6.6 mg/L of AMP.

5. The infant formula composition of claim 1 having a total nucleotide concentration of 12.4 mg/L to 37.4 mg/L.

6. The infant formula composition of claim 5 having a total nucleotide concentration of 15.5 mg/L to 24.9 mg/L.

7. A method of feeding preterm infants comprising feeding said infant a nutritionally sufficient amount of the infant formula composition of claim 1.

IX. Evidence Appendix

The following are appended hereto:

A. 35 U.S.C. 102(b)

B. 35 U.S.C. 103(a)

C. U.S. Pat. No. 5,066,500

D. U.S. Pat. No. 6,913,778

E. Schering Corp. v. Geneva Pharmaceuticals, Inc., 67 USPQ2d 1664 (Fed. Cir. 2003).

35 U.S.C. 102 Conditions for patentability; novelty and loss of right to patent.

A person shall be entitled to a patent unless ...

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States....

35 U.S.C. 103 Conditions for patentability; non-obvious subject matter.

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

tive marks in connection with such closely related articles of apparel is likely to cause confusion.

Decision: The refusal under Section 2(d) is reversed.

Schering Corp. v. Geneva Pharmaceuticals Inc.

U.S. Court of Appeals
Federal Circuit

Nos. 02-1540 through 02-1549, 03-1021, -1022, -1023, -1025, -1027

Decided August 1, 2003

PATENTS

[1] Patentability/Validity — Anticipation — Prior art (§ 115.0703)

Inherent anticipation does not require that person of ordinary skill in art at relevant time would have recognized inherent disclosure.

[2] Patentability/Validity — Anticipation — Prior art (§ 115.0703)

Patentability/Validity — Anticipation — Identity of elements (§ 115.0704)

Claimed invention may be inherently anticipated even if prior art supplies no express description of any part of claimed subject matter, since prior art reference that expressly or inherently contains each and every limitation of claimed subject matter anticipates and invalidates, and there is no reason to modify this general rule in situation in which inherency supplies entire anticipatory subject matter; thus, inherency operates to anticipate entire inventions, as well as single limitations within inventions.

[3] Patentability/Validity — Anticipation — Prior art (§ 115.0703)

Patentability/Validity — Anticipation — Identity of elements (§ 115.0704)

Prior patent for antihistamine loratadine is anticipatory prior art reference to patent covering metabolite of loratadine called descarboethoxyloratadine or "DCL," even if secret tests of loratadine failed to place DCL in public domain prior to critical date for patent in suit, since anticipation requires only enabling disclosure of prior art subject matter, not actual creation or reduction to practice, since, to qualify as enabled reference, prior patent need only describe how to make DCL in any form encompassed by compound claim covering DCL, including DCL as metabolite in patient's body, since prior patent discloses administering loratadine to patient, and since inherent result of administering loratadine to patient is formation of DCL.

[4] Patentability/Validity — Anticipation — Identity of elements (§ 115.0704)

Federal district court, in granting summary judgment that prior art patent for antihistamine loratadine inherently anticipates claims covering metabolite of loratadine called descarboethoxyloratadine or "DCL," correctly concluded that ingestion of loratadine necessarily produces DCL metabolite, since record contains extensive evidence from clinical studies showing that ingestion of loratadine by humans forms DCL, since patentee's technical articles and filings with regulatory agencies referred to DCL as metabolite of loratadine, since U.S. Food and Drug Administration, corresponding European agency, and patentee's package insert for its approved loratadine product all referred to DCL as major metabolite of loratadine, and since patentee's own expert testified that there is no scientific data stating that DCL is not formed from loratadine in humans.

Particular patents — Chemical — Antihistamines

4,659,716, Villani and Wong, antihistaminic 8-(halo)-substituted 6,11-dihydro-11-(4-piperidylidene)-5H-benzo[5,6]cyclohepta[1,2-b]pyridines, judgment holding claims 1 and 3 invalid affirmed.

Appeal from the U.S. District Court for the District of New Jersey, Bissell, C.J.; 64 USPQ2d 1032.

Consolidated actions by Schering Corp. against Geneva Pharmaceuticals Inc., Novartis Corp., TEVA Pharmaceuticals USA Inc., An-

drx Corp., Andrx Pharmaceuticals I drx Pharmaceuticals Inc., and Mylan ceuticals Inc.; Wyeth, ESI-Lederl Pharmaceuticals, and Wyeth Healthcare (formerly American Ho ucts Inc., Wyeth-Ayerst Laborato Whitehall Robbins Healthcare); an Laboratories Inc., Apotex Inc. Pharma, Copley Pharmaceutical Genpharm Inc. for patent infringem tiff appeals from summary judgmen idity. Affirmed.

Robert G. Krupka, of Kirkland & Angeles, Calif.; David P. Swenson land & Ellis, Washington, D.C.; Joh marais, Sandra A. Bresnick, Peter J Maxine Y. Graham, Monica V. Bha and Young J. Park, of Kirkland & York, N.Y.; John F. Hoffman a Mann, of Schering Corp., Kenilw for plaintiff-appellant.

Robert D. Bajefsky, Barbara R and Matthew J. Mason, of Finnega son, Farabow, Garrett & Dunner, W David A. Manspeizer and Lawrenc of Wyeth, Madison, N.J., for appellees Wyeth, ESI-Lederle, Wye ceuticals, and Wyeth Consumer Julie A. Petruzzelli, Peter J. Curtin E. Gray, of Venable, Baetjer, How letti, Washington, for defendant-a pax Laboratories Inc.; Edgar H. H G. Brown, and Porter F. Fleming, Lawrence & Haug, New York, fo appellee Genpharm Inc.; Colin wood, of Soloman, Zauderer, Frischer & Sharp, New York, for appellees Andrx Corp., Andrx F cals, and Andrx Pharmaceuticals thony Figg and Joseph A. Hynds, Figg, Ernst & Manbeck, Was defendant-appellee Mylan Pha Inc.

Robert S. Silver and William J Caesar, Rivise, Bernstein, Coh tilow, Philadelphia, Pa., for appellees Apotex Inc. and Novex

Thomas L. Creel, Frederick I Keith A. Zullow, of Goodwin I York, for defendants-appellees T ceuticals USA Inc. and Copely cal Inc.

drx Corp., Andrx Pharmaceuticals LLC, Andrx Pharmaceuticals Inc., and Mylan Pharmaceuticals Inc.; Wyeth, ESI-Lederle, Wyeth Pharmaceuticals, and Wyeth Consumer Healthcare (formerly American Home Products Inc., Wyeth-Ayerst Laboratories, and Whitehall Robbins Healthcare); and IMPAX Laboratories Inc., Apotex Inc., Novex Pharma, Copley Pharmaceutical Inc., and Genpharm Inc. for patent infringement. Plaintiff appeals from summary judgment of invalidity. Affirmed.

Robert G. Krupka, of Kirkland & Ellis, Los Angeles, Calif.; David P. Swenson, of Kirkland & Ellis, Washington, D.C.; John M. Desmarais, Sandra A. Bresnick, Peter J. Armenio, Maxine Y. Graham, Monica V. Bhattacharyya, and Young J. Park, of Kirkland & Ellis, New York, N.Y.; John F. Hoffman and Arthur Mann, of Schering Corp., Kenilworth, N.J., for plaintiff-appellant.

Robert D. Bajefsky, Barbara R. Rudolph, and Matthew J. Mason, of Finnegan, Henderson, Farabow, Garrett & Dunner, Washington; David A. Manspeizer and Lawrence Alaburda, of Wyeth, Madison, N.J., for defendants-appellees Wyeth, ESI-Lederie, Wyeth Pharmaceuticals, and Wyeth Consumer Healthcare; Julie A. Petruzzelli, Peter J. Curtin, and James E. Gray, of Venable, Baetjer, Howard & Civiletti, Washington, for defendant-appellee Impax Laboratories Inc.; Edgar H. Haug, Daniel G. Brown, and Porter F. Fleming, of Frommer Lawrence & Haug, New York, for defendant-appellee Genpharm Inc.; Colin A. Underwood, of Soloman, Zauderer, Ellenhorn, Frischer & Sharp, New York, for defendants-appellees Andrx Corp., Andrx Pharmaceuticals, and Andrx Pharmaceuticals Inc.; E. Anthony Figg and Joseph A. Hynds, of Rothwell, Figg, Ernst & Manbeck, Washington, for defendant-appellee Mylan Pharmaceuticals Inc.

Robert S. Silver and William J. Castillo, of Caesar, Rivise, Bernstein, Cohen & Pokotilow, Philadelphia, Pa., for defendants-appellees Apotex Inc. and Novex Pharma.

Thomas L. Creel, Frederick H. Rein, and Keith A. Zullow, of Goodwin Procter, New York, for defendants-appellees Teva Pharmaceuticals USA Inc. and Copely Pharmaceutical Inc.

Douglass C. Hochstetler, Patricia J. Thompson, and Jo-Anne M. Kokoski, of Schiff, Hardin & Waite, Chicago, Ill.; Kevin M. Flowers, of Marshall Gerstein & Borun, Chicago, for defendants-appellees Geneva Pharmaceuticals Inc. and Novartis Corp.

Before Rader, circuit judge, Plager, senior circuit judge, and Bryson, circuit judge.

Rader, J.

On summary judgment, the United States District Court for the District of New Jersey determined that claims 1 and 3 of U.S. Patent No. 4,659,716 (the '716 patent) are invalid. *Schering Corp. v. Geneva Pharm., Inc.*, No. 98-1259 [64 USPQ2d 1032] (D.N.J. Aug. 8, 2002). Because the district court correctly found that U.S. Patent No. 4,282,233 (the '233 patent) inherently anticipates claims 1 and 3 of the '716 patent, this court affirms.

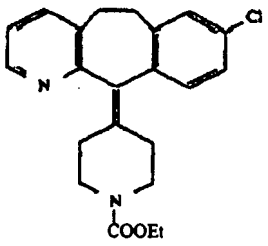
I.

Schering Corporation (Schering) owns the '233 and '716 patents on antihistamines. Antihistamines inhibit the histamines that cause allergic symptoms.

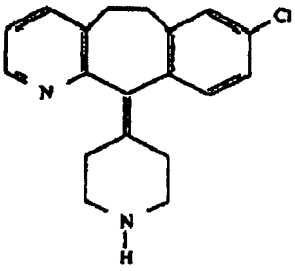
The prior art '233 patent covers the antihistamine loratadine, the active component of a pharmaceutical that Schering markets as CLARITIN®. Unlike conventional antihistamines when CLARITIN® was launched, loratadine does not cause drowsiness.

The more recent '716 patent at issue in this case covers a metabolite of loratadine called descarboethoxyloratadine (DCL). A metabolite is the compound formed in the patient's body upon ingestion of a pharmaceutical. The ingested pharmaceutical undergoes a chemical conversion in the digestion process to form a new metabolite compound. The metabolite DCL is also a non-drowsy antihistamine. The '716 patent issued in April 1987 and will expire in April 2004 (the '233 patent issued in 1981 and has since expired). *See* 35 U.S.C. § 154(c)(1) (2000) (defining the term of a patent in force before June 8, 1995, as the greater of twenty years from the earliest U.S. priority date or seventeen years from grant).

Structurally, loratadine and its metabolite DCL differ only in that loratadine has a carboethoxy group (i.e., COOEt) on a ring nitrogen, while DCL has a hydrogen atom on that ring nitrogen:



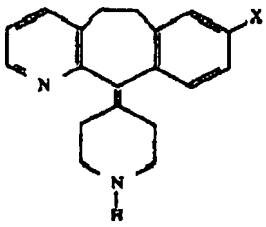
Loratadine ('233 patent)



DCL ('716 patent)

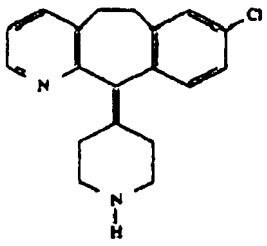
Claim 1 of the '716 patent covers DCL (for X = Cl), its fluorine analog, and their salts; claim 3 covers only DCL and its salts:

1. A compound of the formula



or a pharmaceutically acceptable salt thereof, wherein X represents Cl or F.

3. A compound having the structural formula



or a pharmaceutically acceptable salt thereof.

The '233 patent issued on August 4, 1981, over one year before the earliest priority date of the '716 patent, February 15, 1984. The '233 patent is thus prior art to the '716 patent. *See* 35 U.S.C. § 102(b) (2000) ("A person shall be entitled to a patent unless . . . the invention was patented . . . in this or a foreign country . . . more than one year prior to the date of the application for patent in the United States."). The '233 patent discloses a class of compounds including loratadine (disclosed in Example 1B). '233 patent, col. 3, ll. 5-12. The '233 patent claims loratadine in claim 7. *Id.*, col. 6, ll. 38-40. The '233 patent claims four other compounds in claims 8-11. Examples 6-7 are prophetic[1] examples of pharmaceutical compositions (a syrup and a tablet), each containing an unidentified "active compound." The '233 patent does not expressly disclose DCL and does not refer to metabolites of loratadine.

The numerous defendants-appellees sought to market generic versions of loratadine once the '233 patent expired. Seeking regulatory approval, each appellee submitted an application to the Food and Drug Administration (FDA). *See* 21 U.S.C. § 355(b), (j) (2000). Because Schering included the '716 patent in the Orange Book listing for loratadine, the applications also contained a certification that the '716 patent was invalid. *See id.* § 355(b)(2)(A), 355(j)(2)(A)(vii). The appellees notified Schering of the FDA filings. *See id.* § 355(b)(3)(B), 355(j)(2)(B)(ii).

After receiving notice of the FDA filings, Schering filed suit for infringement. *See* 35 U.S.C. § 271(e)(2)(A) (2000). After discovery, the parties filed cross motions for summary judgment on the validity issue. The district court construed claims 1 and 3 of the '716 patent to cover DCL in all its forms, including "metabolized within the human body" and "synthetically produced in a purified and isolated form." The parties agreed to that construction. Applying that claim construction, the district court found that the '233 patent did not expressly disclose DCL. Nonetheless, the

[1] Prophetic examples are set forth in the present tense to indicate that they were not carried out. *Atlas Powder Co. v. E. I. Du Pont de Nemours & Co.*, 750 F.2d 1569, 1578 [224 USPQ 409] (Fed. Cir. 1984).

district court also found that DCL v sarily formed as a metabolite by ca the process disclosed in the '233 p district court concluded that the " anticipated claims 1 and 3 of the " under 35 U.S.C. § 102(b). The dis therefore granted the appellees' m summary judgment of invalidity. timely appealed to this court under § 1295(a)(1) (2000).

II.

This court reviews a grant o judgment without deference. *Telem Corp. v. Topp Telecom, Inc.*, 247 1323 [58 USPQ2d 1545] (Fed. Ci reviewing a summary judgment tion, this court draws all reasonabl in favor of the non-movant. *Ande erty Lobby, Inc.*, 477 U.S. 242, 25

A.

A patent is invalid for antic single prior art reference disclos every limitation of the claime *Lewmar Marine, Inc. v. Barient, I* 744, 747 [3 USPQ2d 1766] (Fed Moreover, a prior art reference m without disclosing a feature of th vention if that missing characteri sarily present, or inherent, in the pating reference. *Continental Ca santo Co.*, 948 F.2d 1264, 1268 1746] (Fed. Cir. 1991).

[1] At the outset, this court re tention that inherent anticipation ognition in the prior art. Scher *Elan Pharmaceuticals, Inc. v. M tion for Medical Education & F* F.3d 1221 (Fed. Cir. 2002) for tion. This court has since vacat 314 F.3d 1299 (Fed. Cir. 2002). dents of this court have held tha ticipation does not require that a dinary skill in the art at the tim recognized the inherent disclosu *Cruciferous Sprout Litig.*, 30 1351 [64 USPQ2d 1202] (Fed *Mehl/Biophile Int'l Corp. v. M* F.3d 1362, 1366 [52 USPQ2d 1 1999) ("Where . . . the result i consequence of what was de tended, it is of no import that th thors did not appreciate the re

district court also found that DCL was necessarily formed as a metabolite by carrying out the process disclosed in the '233 patent. The district court concluded that the '233 patent anticipated claims 1 and 3 of the '716 patent under 35 U.S.C. § 102(b). The district court therefore granted the appellees' motions for summary judgment of invalidity. Schering timely appealed to this court under 28 U.S.C. § 1295(a)(1) (2000).

II.

This court reviews a grant of summary judgment without deference. *Telemac Cellular Corp. v. Topp Telecom, Inc.*, 247 F.3d 1316, 1323 [58 USPQ2d 1545] (Fed. Cir. 2001). In reviewing a summary judgment determination, this court draws all reasonable inferences in favor of the non-movant. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986).

A.

A patent is invalid for anticipation if a single prior art reference discloses each and every limitation of the claimed invention. *Lewmar Marine, Inc. v. Barient, Inc.*, 827 F.2d 744, 747 [3 USPQ2d 1766] (Fed. Cir. 1987). Moreover, a prior art reference may anticipate without disclosing a feature of the claimed invention if that missing characteristic is necessarily present, or inherent, in the single anticipating reference. *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268 [20 USPQ2d 1746] (Fed. Cir. 1991).

[1] At the outset, this court rejects the contention that inherent anticipation requires recognition in the prior art. Schering relies on *Elan Pharmaceuticals, Inc. v. Mayo Foundation for Medical Education & Research*, 304 F.3d 1221 (Fed. Cir. 2002) for that proposition. This court has since vacated *Elan*. *See* 314 F.3d 1299 (Fed. Cir. 2002). Other precedents of this court have held that inherent anticipation does not require that a person of ordinary skill in the art at the time would have recognized the inherent disclosure. *E.g., In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1351 [64 USPQ2d 1202] (Fed. Cir. 2002); *Mehl/Biophile Int'l Corp. v. Milgraum*, 192 F.3d 1362, 1366 [52 USPQ2d 1303] (Fed. Cir. 1999) ("Where . . . the result is a necessary consequence of what was deliberately intended, it is of no import that the article's authors did not appreciate the results."); *Atlas Powder*, 190 F.3d at 1348-49 ("Because 'sufficient aeration' was inherent in the prior art, it is irrelevant that the prior art did not recognize the key aspect of [the] invention. . . . An inherent structure, composition, or function is not necessarily known."). Thus, recognition by a person of ordinary skill in the art before the critical date of the '716 patent is not required to show anticipation by inherency. The district court therefore did not err in allowing for later recognition of the inherent characteristics of the prior art '233 patent.

Contrary to Schering's contention, *Continental Can* does not stand for the proposition that an inherent feature of a prior art reference must be perceived as such by a person of ordinary skill in the art before the critical date. In *Continental Can*, this court vacated summary judgment of anticipation of claims reciting a plastic bottle with hollow ribs over a prior art reference disclosing a plastic bottle. The record contained conflicting expert testimony about whether the ribs of the prior art plastic bottle were solid. The accused infringer's expert testified that the prior art plastic bottle was made by blow molding, a process that would inherently produce hollow ribs. The patentee's experts testified that the prior art plastic bottle had solid ribs. The patentee disputed whether the blow molding inherently produced hollow ribs. Given the disputed material fact, this court vacated the summary judgment as improper. *Continental Can*, 948 F.2d at 1269. *Continental Can* makes no reference to whether the inherent feature, hollow ribs, was recognized before or after the critical date of the patent at issue. Read in context, *Continental Can* stands for the proposition that inherency, like anticipation itself, requires a determination of the meaning of the prior art. Thus, a court may consult artisans of ordinary skill to ascertain their understanding about subject matter disclosed by the prior art, including features inherent in the prior art. A court may resolve factual questions about the subject matter in the prior art by examining the reference through the eyes of a person of ordinary skill in the art, among other sources of evidence about the meaning of the prior art. Thus, in *Continental Can*, this court did not require past recognition of the inherent feature, but only allowed recourse to opinions of skilled artisans to determine the scope of the prior art reference.

Cases dealing with "accidental, unwitting, and unappreciated" anticipation also do not show that inherency requires recognition. *See Eibel Process Co. v. Minn. & Ontario Paper Co.*, 261 U.S. 45 (1923); *Tilghman v. Proctor*, 102 U.S. 707 (1880). In contrast to the present case, the record in *Eibel* and *Tilghman* did not show that the prior art produced the claimed subject matter. The patent at issue in *Tilghman* claimed a method of forming free fatty acids and glycerine by heating fats with water at high pressure. In *Tilghman*, the record did not show conclusively that the claimed process occurred in the prior art. In reviewing the prior art, the Court referred hypothetically to possible disclosure of the claimed process. For example, the Court stated "[w]e do not regard the accidental formation of fat acid in Perkins's steam cylinder . . . (if the scum which rose on the water issuing from the ejection pipe was fat acid) as of any consequence in this inquiry." *Tilghman*, 102 U.S. at 711. In *Eibel*, the Court found no evidence of the claimed subject matter in the prior art. *Eibel*, 261 U.S. at 66 ("[W]e find no evidence that any pitch of the wire . . . had brought about such a result . . . and . . . if it had done so under unusual conditions, accidental results, not intended and not appreciated, do not constitute anticipation.").

Applying an inherency principle in the context of an on sale bar under 35 U.S.C. § 102(b), this court has distinguished *Eibel* and *Tilghman*. *See Abbott Labs. v. Geneva Pharms., Inc.*, 182 F.3d 1315, 1319 [51 USPQ2d 1307] (Fed. Cir. 1999) ("If a product that is offered for sale inherently possesses each of the limitations of the claims, then the invention is on sale, whether or not the parties to the transaction recognize that the product possesses the claimed characteristics."); *Scaltech, Inc. v. Retec/Tetra, LLC*, 269 F.3d 1321, 1330 [60 USPQ2d 1687] (Fed. Cir. 2001) ("[A]ppreciation of the invention is not a requirement to trigger the statutory [on sale] bar."). In those cases, the product sold or offered for sale had an inherent, but unrecognized, feature that was a limitation of the asserted claims. *Id.* Thus, this court has distinguished *Eibel* and *Tilghman*, which therefore do not bind this court to find no anticipation because skilled artisans did not recognize that the prior art '233 patent inherently produced the claimed invention, DCL.

In the context of accidental anticipation, DCL is not formed accidentally or under unusual conditions when loratadine is ingested. The record shows that DCL necessarily and inevitably forms from loratadine under normal conditions. DCL is a necessary consequence of administering loratadine to patients. The record also shows that DCL provides a useful result, because it serves as an active, non-drowsy antihistamine. In sum, this court's precedent does not require a skilled artisan to recognize the inherent characteristic in the prior art that anticipates the claimed invention.

B.

This court recognizes that this may be a case of first impression, because the prior art supplies no express description of any part of the claimed subject matter. The prior art '233 patent does not disclose any compound that is identifiable as DCL. In this court's prior inherency cases, a single prior art reference generally contained an incomplete description of the anticipatory subject matter, i.e., a partial description missing certain aspects. Inherency supplied the missing aspect of the description. Upon proof that the missing description is inherent in the prior art, that single prior art reference placed the claimed subject matter in the public domain. This case does not present the issue of a missing feature of the claimed invention. Rather, the new structure in this case, DCL, is not described by the prior '233 patent.

[2] Patent law nonetheless establishes that a prior art reference which expressly or inherently contains each and every limitation of the claimed subject matter anticipates and invalidates. *See, e.g., EMI Group N. Am., Inc. v. Cypress Semiconductor Corp.*, 268 F.3d 1342, 1350 [60 USPQ2d 1423] (Fed. Cir. 2001) ("A prior art reference anticipates a patent claim if the reference discloses, either expressly or inherently, all of the limitations of the claim."); *Verdegaal Bros., Inc. v. Union Oil Co. of Cal.*, 814 F.2d 628, 631 [2 USPQ2d 1051] (Fed. Cir. 1987) ("A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."). In these prior cases, however, inherency was only necessary to supply a single, missing limitation that was not expressly disclosed in the prior art. This case, as explained before,

asks this court to find anticipation when entire structure of the claimed subject ma is inherent in the prior art.

Because inherency places subject matte the public domain as well as an express closure, the inherent disclosure of the e claimed subject matter anticipates as we inherent disclosure of a single feature of claimed subject matter. The extent of th herent disclosure does not limit its anti tory effect. In general, a limitation or th tire invention is inherent and in the publi main if it is the "natural result flowing fr the explicit disclosure of the prior art. *Se Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 970 [58 USPQ2d 1865] (Fed. Cir. 2001 *also In re Kratz*, 592 F.2d 1169, 1174 USPQ 71] (CCPA 1979) (suggesting inh anticipation of a compound even thoug compound's existence was not known).

In reaching this conclusion, this co aware of *In re Seaborg*, 328 F.2d 99(USPQ 662] (CCPA 1964). In that cas court's predecessor considered claims to an isotope of americium made by r reaction in light of a prior art patent d ing a similar nuclear reaction process b no disclosure of the claimed isotop court reversed a United States Pate Trademark Office rejection of the cla lack of novelty. This court's pred found that the prior art process did no pate the claims because the process have produced at most one billionth of of the isotope in forty tons of radioact terial, i.e., the isotope would have bee tectable. *Id.* at 998-99 ("[T]he claim uct, if it was produced in the Fermi was produced in such minuscule amo under such conditions that its prese undetectable."). In this case, DCL readily detectable amounts as show extensive record evidence of testing humans to verify the formation of D ingestion of loratadine.

This court sees no reason to m general rule for inherent anticipation where inherency supplies the entire tory subject matter. The patent law "that which would literally infringe time anticipates if earlier," *Bris Squibb Co. v. Ben Venue Labs., Inc.* 1368, 1378 [58 USPQ2d 1508] 2001), bolsters this conclusion. Sin

asks this court to find anticipation when the entire structure of the claimed subject matter is inherent in the prior art.

Because inherency places subject matter in the public domain as well as an express disclosure, the inherent disclosure of the entire claimed subject matter anticipates as well as inherent disclosure of a single feature of the claimed subject matter. The extent of the inherent disclosure does not limit its anticipatory effect. In general, a limitation or the entire invention is inherent and in the public domain if it is the "natural result flowing from" the explicit disclosure of the prior art. *See Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 970 [58 USPQ2d 1865] (Fed. Cir. 2001); *see also In re Kratz*, 592 F.2d 1169, 1174 [201 USPQ 71] (CCPA 1979) (suggesting inherent anticipation of a compound even though the compound's existence was not known).

In reaching this conclusion, this court is aware of *In re Seaborg*, 328 F.2d 996 [140 USPQ 662] (CCPA 1964). In that case, this court's predecessor considered claims drawn to an isotope of americium made by nuclear reaction in light of a prior art patent disclosing a similar nuclear reaction process but with no disclosure of the claimed isotope. The court reversed a United States Patent and Trademark Office rejection of the claims for lack of novelty. This court's predecessor found that the prior art process did not anticipate the claims because the process would have produced at most one billionth of a gram of the isotope in forty tons of radioactive material, i.e., the isotope would have been undetectable. *Id.* at 998-99 ("[T]he claimed product, if it was produced in the Fermi process, was produced in such minuscule amounts and under such conditions that its presence was undetectable."). In this case, DCL forms in readily detectable amounts as shown by the extensive record evidence of testing done on humans to verify the formation of DCL upon ingestion of loratadine.

This court sees no reason to modify the general rule for inherent anticipation in a case where inherency supplies the entire anticipatory subject matter. The patent law principle "that which would literally infringe if later in time anticipates if earlier," *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1378 [58 USPQ2d 1508] (Fed. Cir. 2001), bolsters this conclusion. Similarly, "if granting patent protection on the disputed claim would allow the patentee to exclude the public from practicing the prior art, then that claim is anticipated." *Atlas Powder*, 190 F.3d at 1346. "The public remains free to make, use, or sell prior art compositions or processes, regardless of whether or not they understand their complete makeup or the underlying scientific principles which allow them to operate. The doctrine of anticipation by inherency, among other doctrines, enforces that basic principle." *Id.* at 1348. Thus, inherency operates to anticipate entire inventions as well as single limitations within an invention.

Turning to this case, the use of loratadine would infringe claims 1 and 3 of the '716 patent covering the metabolite DCL. This court has recognized that a person may infringe a claim to a metabolite if the person ingests a compound that metabolizes to form the metabolite. *See Hoechst-Roussel Pharms., Inc. v. Lehman*, 109 F.3d 756, 759 [42 USPQ2d 1220] (Fed. Cir. 1997) ("[T]he right to exclude may arise from the fact that when administered, [the accused product] metabolizes into another product . . . which Hoechst has claimed."); *see also Zenith Labs., Inc. v. Bristol-Myers Squibb Co.*, 19 F.3d 1418, 1421-22 [30 USPQ2d 1285] (Fed. Cir. 1994) (stating that a compound claim could cover a compound formed upon ingestion). An identical metabolite must then anticipate if earlier in time than the claimed compound.

The record shows that the metabolite of the prior art loratadine is the same compound as the claimed invention. Claims 1 and 3 are compound claims in which individual compounds are claimed in the alternative in Markush format. DCL is within the scope of claims 1 and 3. Because the prior art metabolite inherently disclosed DCL, claims 1 and 3 are anticipated and invalid. In other words, the record shows that a patient ingesting loratadine would necessarily metabolize that compound to DCL. That later act would thus infringe claims 1 and 3. Thus, a prior art reference showing administration of loratadine to a patient anticipates claims 1 and 3.

C.

This court next examines whether Schering's secret tests of loratadine before the critical date placed DCL in the public domain. Before the critical date, Schering only tested lo-

ratadine in secret. Thus, according to Schering, "DCL was not publicly used, or described in any printed publication, until after February 15, 1983, the critical date for the '716 patent under 35 U.S.C. § 102(b)." Schering thus argues that DCL did not "exist" in the public domain such that DCL could be prior art against the '716 patent.

[3] Anticipation does not require the actual creation or reduction to practice of the prior art subject matter; anticipation requires only an enabling disclosure. *In re Donohue*, 766 F.2d 531, 533 [226 USPQ 619] (Fed. Cir. 1985). Thus, actual administration of loratadine to patients before the critical date of the '716 patent is irrelevant. The '233 patent suffices as an anticipatory prior art reference if it discloses in an enabling manner the administration of loratadine to patients.

Thus, this court examines whether the '233 patent contains an enabling disclosure of DCL. A reference may enable one of skill in the art to make and use a compound even if the author or inventor did not actually make or reduce to practice that subject matter. *Bristol-Myers*, 246 F.3d at 1379; *see also In re Donohue*, 766 F.2d at 533 (sustaining an anticipation rejection over a reference disclosing a compound and other references disclosing sufficient information to make that compound). Indeed, information arising after the critical date may show that the claimed subject matter, as disclosed in a prior art reference, "was in the public's possession." *Bristol-Myers*, 246 F.3d at 1379 (citing *In re Donohue*, 766 F.2d at 534).

An anticipatory reference need only enable subject matter that falls within the scope of the claims at issue, nothing more. To qualify as an enabled reference, the '233 patent need not describe how to make DCL in its isolated form. The '233 patent need only describe how to make DCL in any form encompassed by a compound claim covering DCL, e.g., DCL as a metabolite in a patient's body. The '233 patent discloses administering loratadine to a patient. A person of ordinary skill in the art could practice the '233 patent without undue experimentation. The inherent result of administering loratadine to a patient is the formation of DCL. The '233 patent thus provides an enabling disclosure for making DCL.

D.

Finally, this court's conclusion on inherent anticipation in this case does not preclude patent protection for metabolites of known drugs. With proper claiming, patent protection is available for metabolites of known drugs. *Cf. In re Kratz*, 592 F.2d 1169, 1174 [201 USPQ 71] (CCPA 1979) (stating that a naturally occurring strawberry constituent compound does not anticipate claims to the substantially pure compound); *In re Bergstrom*, 427 F.2d 1394, 1401-02 [166 USPQ 256] (CCPA 1970) (stating that a material occurring in nature in less pure form does not anticipate claims to the pure material).

But those metabolites may not receive protection via compound claims. In this case, for instance, claims 1 and 3 broadly encompass compounds defined by structure only. Such bare compound claims include within their scope the recited compounds as chemical species in any surroundings, including within the human body as metabolites of a drug. As this case holds, these broad compound claims are inherently anticipated by a prior art disclosure of a drug that metabolizes into the claimed compound.

A skilled patent drafter, however, might fashion a claim to cover the metabolite in a way that avoids anticipation. For example, the metabolite may be claimed in its pure and isolated form, as in *Kratz* and *Bergstrom*, or as a pharmaceutical composition (e.g., with a pharmaceutically acceptable carrier). The patent drafter could also claim a method of administering the metabolite or the corresponding pharmaceutical composition. The '233 patent would not provide an enabling disclosure to anticipate such claims because, for instance, the '233 patent does not disclose isolation of DCL.

The '716 patent contains claims 5-13 covering pharmaceutical compositions and claims 14-16 covering methods of treating allergic reactions by administering compounds that include DCL. These claims were not found anticipated by the '233 patent.

III.

The district court found that "there is no genuine issue that the consumption of loratadine by humans, with a wide variety of health statuses, necessarily results in the natural production in the human body of the DCL me-

tabolite." This court must also examine record for any genuine issue of material about whether ingestion of loratadine n sarily produces DCL. The record does, fo stance, contain expert testimony, includi proposed metabolic scheme, and animal that questions whether ingestion of lorata always forms DCL.

[4] A dispute about a material fact is g ine "if the evidence is such that a reaso jury could return a verdict for the nonmo party." *Anderson v. Liberty Lobby, Inc.*, U.S. 242, 248 (1986). In this case, the dence supporting the district court's co sion is extensive. In thirteen clinical st that Schering ran before May 1, 1987, al patients involved had measurable amoun DCL in their systems after ingesting lo dine. The district court found "no repo any of the studies of any individual wh not metabolically produce DCL followin administration of loratadine." The app reported twenty-one clinical studies in w loratadine was administered to a total of patients, all of whom formed me amounts of DCL in their systems. In f the record shows that since 1985 Sc technical articles and Securities and Commission filings referred to DC metabolite of loratadine. Also the Drug Administration, the corresp pean agency, the Physician's Des and Schering's CLARITIN® p referred to DCL as the major m ratadine.

"The record presents no da show that a genuine factu about the formation of DCL ratadine. Indeed, Schering fied that no human has be not metabolize loratadine "[t]here is no scientific d literature that says that DC from loratadine in humans record, no reasonable jur DCL is not produced wh loratadine. This court th genuine issue of material

CONCLUSI

The district court did the '233 patent discloses dine to a patient, and t natural result of that ad

tabolite." This court must also examine the record for any genuine issue of material fact about whether ingestion of loratadine necessarily produces DCL. The record does, for instance, contain expert testimony, including a proposed metabolic scheme and animal data, that questions whether ingestion of loratadine always forms DCL.

[4] A dispute about a material fact is genuine "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). In this case, the evidence supporting the district court's conclusion is extensive. In thirteen clinical studies that Schering ran before May 1, 1987, all 144 patients involved had measurable amounts of DCL in their systems after ingesting loratadine. The district court found "no reports in any of the studies of any individual who did not metabolically produce DCL following the administration of loratadine." The appellees reported twenty-one clinical studies in which loratadine was administered to a total of 864 patients, all of whom formed measurable amounts of DCL in their systems. In addition, the record shows that since 1985 Schering's technical articles and Securities and Exchange Commission filings referred to DCL as the metabolite of loratadine. Also the Food and Drug Administration, the corresponding European agency, the Physician's Desk Reference, and Schering's CLARITIN® package insert referred to DCL as the major metabolite of loratadine.

The record presents no data on humans to show that a genuine factual dispute exists about the formation of DCL after ingesting loratadine. Indeed Schering's own expert testified that no human has been found that does not metabolize loratadine to DCL, and that "[t]here is no scientific data in the published literature that says that DCL is not formed from loratadine in humans." Based on this record, no reasonable jury could find that DCL is not produced when a human ingests loratadine. This court therefore discerns no genuine issue of material fact.

CONCLUSION

The district court did not err in finding that the '233 patent discloses administering loratadine to a patient, and that DCL forms as a natural result of that administration. The district court correctly concluded that DCL is inherent in the prior art. Without any genuine issues of material fact, the district court correctly granted summary judgment that claims 1 and 3 are invalid as anticipated by the '233 patent.

COSTS

Each party shall bear its own costs.

AFFIRMED

National Diamond Syndicate Inc. v. Flanders Diamond USA Inc.

U.S. District Court
Northern District of Illinois

No. 00 C 6402

Decided July 14, 2003

PATENTS

[1] Practice and procedure in Patent and Trademark Office — Prosecution — Duty of candor — Materiality (§ 110.0903.04)

Infringement — Defenses — Fraud or unclean hands (§ 120.1111)

Inventor engaged in inequitable conduct during prosecution of design patent by failing to disclose prior art patent for gemstone design, since prior art design is clearly material, in that it anticipates design claimed in patent in suit, since prior patent is not merely cumulative of other information considered by patent examiner, in that written description and claims refer to square versions of design, as well as rectangular version considered by examiner, since testimony and other evidence established that inventor chose not to disclose prior patent despite fact that he had knowledge of prior art design itself, as well as prior inventor's claim that design of patent in suit was unauthorized copy, and since evidence further established that inventor knew of square versions of prior art design, that said design was very similar to that claimed in patent in suit, and that prior inventor had obtained some form of intellectual property protection; even if inventor's conduct is deemed to be merely gross negligence, there is no